

Meeting Reports



Regulations In Practice

Medical Information
5th November, London

Morning Session

By: Mary Cockburn, Medical Affairs Associate, Biogen Idec UK and Ireland.

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the new rights is likely to include that an electronic subscription will count as having the original.

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The ABPI Code By Dr Joan Barnard

Joan Barnard is well known in our Pharmaceutical Industry as an expert on the Association of the British Pharmaceutical Industry (ABPI) Code Of Practice. She is a director of a company aptly called 'Code IN practice'. You may have a copy of her book in your department which has been revised and provides a useful summary of latest (2008) 50 year golden edition of the code.

This UK code incorporates local, European and International Pharmaceutical principles and legislation as well as World Health Organisation criteria. Contrary to popular belief the ABPI is no longer the strictest code (though it is the most detailed).

Ultimately the ABPI code of practice serves to benefit patients by ensuring that our Industry operates in a professional, ethical and transparent manner.

The code covers all activity - promotional and non-promotional. Even with all the many clauses though there are still many 'grey' areas. A quick test is to consider how



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the activity would appear as a stand alone piece should the media publish it- would it bring our industry into disrepute, is it fair, balanced and accurate.

I thought it worth sharing one of the interesting discussions covered;

Q. If a patient contacts medical information and asks for information outside of the scope of the code, it is usual to refer them back to their treating health care professional (HCP) However can we offer to provide the information directly to their HCP?

Joan Barnard's Answer

- We can ask the patient to ask their HCP to contact Medical information to discuss the information directly.
- Alternatively we can contact their HCP explain their patient has been in contact and offer to provide this information for them to discuss with their patient.
- It was felt it was not appropriate to provide the information proactively

to the HCP without their consent, regardless of whether it was requested by their patient.

Tips

- Check their website www.codeinpractice.co.uk.
- Joan can be contacted at Joan@codeinpractice.co.uk
- Subscribe to updates about Code In Practice services and news about the Code.
- If you have a question about the Code? or how to apply it in practice? Why not use their free, confidential service which is available at the following web address: <http://www.codeinpractice.co.uk/en/1/askusform.html>

Afternoon Session

By: Okanthey Baines, Medical Information Officer, Orion Pharma (UK) Limited

I was quite looking forward to the afternoon session of the training course, as we were looking at the PIPA guidelines on standards for medical information departments. Just to give a few examples, we looked at the procedures for handling enquiries, information resources, qualifications, training, and audits and performance indicators.

Following this insightful session, we were trained on what to expect at inspections, in particular what role Medical information would play within this role. This session benefited us a lot especially for those who were not in this job for that long. It showed us how important it is to liaise and document processes with other departments for when a company undergoes an inspection, may it be internal or external. However, most of us on this

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training day were not purely involved in medical information but also did a bit of everything else, such as regulatory, pharmacovigilance etc.

This session developed into a discussion whereby some of the medical information

officers shared their experiences of inspections, what role they had to play and what to expect, and certainly what to avoid when auditors were wondering around the medical information departments. The main message to take away from this was it's all about PREPARATION.

After our tea break, we had a presentation on NHS changes by Sylvia Barber. She gave us an overview of the NHS changes in the last 60 years. It was interesting to see how the relationship has developed between the pharmaceutical industry and the NHS, especially focusing on the drugs budget.

The day ended with a recap of what we have covered throughout the day. Overall, this course is ideal for anyone who is new to Medical Information.

For more information, Mary can be contacted at mary.cockburn@biogenidec.com and Okanthey at okanthey.baines@orionpharma.com

Pharmacovigilance Day

Regulations In Practice

6th November 2008, London

By: Blessing Manyonga, Drug Safety Officer,
Boehringer Ingelheim Ltd

Summary

Expedited reporting and Safety Surveillance-PSURs, were two of the several topics discussed on the second day of the two-day Regulations in Practice training. Expedited reporting included an update on EU and UK Legislation, E2B reporting and a workshop on MHRA inspections which proved extremely popular amongst the attending delegates.

We were fortunate to have 2 presenters who have a total of 25 years safety experience between them including 2 years at the MHRA, appropriately presenting the session on expedited reporting.

The presentation opened by reminding delegates that pharmaceutical companies are legally obliged to timely report cases to regulators on an expedited basis and periodically. This applies for both pre-marketed and post-marketed products. The session encompassed both EU and UK legislation. We discussed definitions, with examples, of Regulations, Directives and Guidelines highlighting that even though Volume 9A is a Guideline it is a mandatory legal framework for Pharmacovigilance. A summary of the Volume 9A September 2008 update was given which raised a lot of questions and points for discussion.

A lack of efficacy report is expeditable if the lack of efficacy is with a vaccine or life threatening agent. In defining a healthcare professional (HCP) confirmed report, it was felt qualified radiographers and physiotherapists, medical, nursing and pharmacy students were not clearly defined as HCPs. The general consensus from the attending delegates was that registered radiographers and physiotherapist would qualify as HCPs but not the students. If a non HCP reporter provides medical

documentation such as medical /nursing notes in support of an adverse event report, this can be classed as HCP confirmed and therefore is deemed expeditable.

Patient initials are considered as patient identifiers. If initials are known but cannot be entered, PRIVACY should be entered in the field. If initials are unknown then UNKNOWN should be entered. A workshop based on MHRA pharmacovigilance inspections, what the inspectors may ask and what they may look for, in relation to expedited reporting allowed an immediate consolidation of the presentation and our discussions. The workshop was particularly useful in sharing experiences across companies and was very popular with all the delegates.

This was followed by a presentation on E2B reporting. E2B reporting was deemed mandatory since 2005. It was evident in discussions that most companies had not started E2B reporting or even testing. Of course the MHRA are aware, but the presenters encouraged companies to contact the MHRA for an indication of testing dates.

The morning was concluded with a presentation on Periodic Safety Update Reports (PSUR). This provided an overview of PSURs, including a history, regulatory and industry outlook and an update on



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recent developments and pilot schemes. An interactive workshop which prompted plenty of discussion and information exchange amongst the delegates brought the morning to a close.

Conclusion

The sessions were very informative and packed with relevant information. The day was attended by delegates with varied experiences and backgrounds, from 11 different pharmaceutical companies. The course was well pitched for beginners as well as those experienced. Delegates were able to ask questions during the presentations facilitating ongoing discussions and an exchange of ideas and experiences. The presenters were friendly and receptive. They were readily available for questions and discussion during coffee breaks and were happy to be contacted on return to the office.

I thoroughly enjoyed the day, particularly the interactive sessions. I would certainly recommend similar PIPA courses to colleagues.

For more information, Blessing can be contacted at: blessing.gombedza@boehringer-ingelheim.com